

TANIMURA & ANTLE, INC.

P.O. BOX 4070 • SALINAS, CALIFORNIA 93912 • PHONE (408) 455-2950



October 26, 1998

TO: Mr. James R. Rodeheaver
Branch Chief, Processed Products Branch
Fruits & vegetable Programs
AMS, USDA, STOP 0247
P.O. Box 96456
Washington DC 20090-6456

SUBJECT: USDA/QTV

Dear Mr. Rodeheaver:

I am responding to your press release dated September 3, 1998, in which you are seeking input on the Qualified Through Verification (QTV) program.

By now, our three processing facilities are qualified and are regularly audited under the QTV program. Based on our experience with this program, we have found that QTV is the only science based workable program designed to improve food safety in the fresh-cut fruits and vegetable industry. This program addresses safety requirements of raw materials, cooling, storage, transportation, processing and packaging areas. The QTV plan also provides major emphasis on sanitation, employee hygiene, regular training and GMP in the plant.

The safety plan addressed under the QTV program is much more than the standard HACCP program. Under HACCP program there are only few limited Critical Control Points (CCP), but in the QTV safety plan all the major steps of processing including raw material sourcing, storage, processing and shipping are stressed to be equally important.

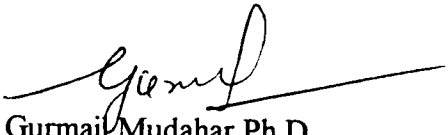
Since the time our facilities are audited under the QTV program, the overall microbial counts of our finished products have significantly decreased. We believe this happened due to the unannounced QTV audits, which required accountability as well as developed competition for improvement in each department of our processing facilities.

We have also found that most of the USDA auditors are very well qualified, friendly and they provide very valuable ideas to further improve the product safety during their visits. QTV program has significantly improved our product safety program. Considering cost of private consultants for food safety program development, this program is cost competitive.

We strongly support this program. Failure of this program may result in a lack of consumer confidence on the fresh fruits and vegetable industry. We feel that every processor of fresh-cut fruits and vegetables should adopt this program. At Tanimura and Antle Inc. this program was driven to improve the safety of our products. Market advantage was never a factor for considering the QTV program for our plants. At this time we are displaying the QTV seal only on some limited items which will not provide significant market advantage to us but it definitely assures that we value our customers and have a commitment to supply safest possible products.

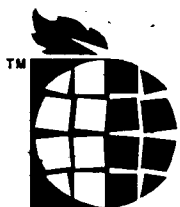
We urge you to maintain this program as one of the high priority USDA-AMS program in order to further improve the safety image of the fresh-cut fruits and vegetable industry. We believe that the American Public deserve the safest possible food supply and hope that the USDA will make this program a requirement for the fresh cut industry. This will improve consumer confidence in the fresh-cut fruits and vegetable industry which will help further develop this industry. Please let us know how we can help USDA to further improve the QTV program and help educate those companies which are hesitant to enroll in this program.

Sincerely,

A handwritten signature in cursive script, appearing to read 'Gurmail', followed by a horizontal line.

Gurmail Mudahar Ph.D.
Director Research & Development

CC: Rick Antle, Ken Silveira



International Fresh-cut Produce Association

November 2, 1998

Office of the Branch Chief
Processed Products Branch
Fruit and Vegetable Programs
Agricultural Marketing Service
USDA, STOP 0247
P.O. Box 96456
Washington, DC 20090-6456

SUBJECT: {Federal Register dated September 4, 1998, Vol. 63, No. 172, pages 47220 to 47224} Comments on the draft Qualified Through Verification (QTV) Program for the Fresh-cut Produce Industry, dated July 1998.

Dear Sir or Madam:

The International Fresh-cut Produce Association (IFPA) submits the following comments on the QTV Program referenced above:

The IFPA has been a long-time supporter of third party audit programs for the fresh-cut produce industry. Our members recognize the benefits of taking an unbiased look at their quality, sanitation and food safety programs and have had a variety of inspectors visit their operations over the years.

In 1994, when the IFPA came to visit the Processed Products Branch of the USDA's Agriculture Marketing Service (AMS), we did not have access to an audit system specifically designed for our particular products. We were primarily looking for help in auditing refrigeration temperatures to help improve the handling practices in the production and distribution of fresh-cut produce. The Department looked at IFPA's food safety materials and designed a program that followed our own food safety guidelines which went beyond temperature audits.

We have since worked together to help clarify the needs and concerns of the industry and to make sure the agency is providing the best service possible to meet those needs. Today, the current draft of the QTV program allows a third party to take a close look at the food safety practices of the processor but still contains some information that falls into the gray area between safety and quality. Those specific areas will be highlighted in the comments section to follow.

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To keep focused on safety, we would urge AMS to analyze whether an audit requirement covers a quality parameter or a safety parameter. We would also remind AMS that our safety practices will continue to change as new developments and scientific information cause us to reformulate our practices to achieve greater safety compliance. Therefore, the QTV program should remain as flexible as possible to be able to reflect the current thinking.

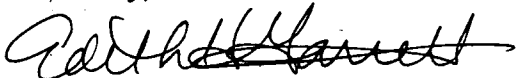
This flexibility needs to be included throughout the plan for another reason, and that is that each processor is different and has a slightly different approach to production. It is important that AMS keep their program as general as possible to take into consideration the many steps, control points and food safety practices they will encounter in the different operations. This QTV plan should outline the general components needed in an operation (e.g., a verified HACCP plan) to complete a successful food safety audit and leave the specifics of how the components are applied up to consideration during the audit.

In addition to the components of the plan, we have concerns about the execution of the plan. We feel that the agency needs to offer the QTV program on an equal basis to each member of the industry that wants to participate. This means that each interested company should have equal access to the inspectors so that they may achieve the goals they set in a timely manner.

We do not feel that there have been enough inspectors available to handle the number of interested participants in order to get them through the program at the same time. There is a backlog of companies on the "interested" list and we hope there is some effort to handle this temporary glut of customers so that they can achieve compliance in a timely manner to maintain an equal position in the marketplace.

Finally, we would like to say that the agency has been very accommodating in working with the industry and we have appreciated the cooperation shown in answering our questions about the program and addressing the issues we have brought up over the last two years. We are confident that the comments that are attached will be addressed in an equally timely and professional manner by the AMS staff. We look forward to working with AMS in the future.

Sincerely,



Edith H. Garrett
President

cc: IFPA Board Members

attach

**Comments on the QTV Program by the International Fresh-cut Produce Association
(IFPA) Page 1 of 3
11/2/98**

- Page 4** **Program Scope** - The scope of this program goes beyond HACCP to include GMPs, sanitation program, product recall plan and microbiological testing, all of which are prerequisites to HACCP. We recommend that the scope be amended to reflect this broad approach to food safety.
- Page 4-5** **Definitions of Critical, Major, Minor and Serious Deficiencies** - These four terms are used throughout the QTV manual and play a very important role in determining the facility rating given after an audit. These represent too many deficiencies and we are concerned that the definitions become watered down if you are trying to determine if a deviation should result in a stop-shipment decision for a product. We recommend that two levels be used, one for unsafe product and one for unsafe practices that will not result in unsafe product. This can provide guidance to the processor so that there is no question about the safety of a product should the system go out of control.
- Page 5** **Definition of HACCP** - We recommend that a reference to the source of your HACCP guidelines be made here to further clarify the principles and definitions to be used by the industry.
- Page 5** **Definition of HACCP-Certified** - This needs to be defined. What certification process is "approved by AMS"?
- Page 5** **Definition of Substantial Risk Products** - This definition implies that all fresh-cut produce is "substantially risky". On what scientific basis does AMS define this? Currently, FDA has only identified three commodities that are "potentially hazardous" when cut and packaged which are mushrooms, melons and garlic stored in oil. We do not believe that FDA considers fresh-cut produce to be potentially hazardous, so we do not agree that these products pose a substantial risk to consumers. The production of these products under unsanitary conditions could lead to a risk but that is different from defining these products as risky in and of themselves. We recommend that the definition be of "potentially hazardous foods" as defined by FDA and all references to this definition be carefully considered before the term is used to identify any fresh-cut product.
- Page 6** **Employee Training** - Again, there needs to be some clarification of the certification process/program for HACCP that AMS will approve.
- Page 8** **Validation Audit** - AMS should state that validation of the company's hazard analysis is the first step of the audit instead of validating that the CCPs have been properly identified. Without referring to what the hazards could be for the particular products being manufactured at the facility, how can CCPs be audited?
- Page 9** **Systems Audit** - It is unclear why there is a reference to "Retail & Food Service"

under Establishment Type if this is indeed an audit program only for the fresh-cut produce industry. Is AMS indeed going to apply this audit program to restaurants and grocery stores? This is not what is implied in other documentation.

- Page 9 **Systems Audit** - Does the number of deficiencies that are allowed imply that they may have occurred but adequate action was taken and the contaminated product was not allowed to be shipped? It is not clear from the limited information in this chart whether the deficiencies are required to be corrected.
- Page 10 **Procedures for Facilities that Fall Below Level IV Facility Rating** - We are concerned that a facility can fall below the lowest rating (Level IV) and still be using the USDA shield for up to 30 days. When there are 3 - 4 "serious deviations" allowed for Level IV performance is this a realistic approach? Is there a more appropriate way to address a drop in performance than allowing the facility to get to the lowest level before taking action?
- Page 11 **Microbiological Testing in the Facility** - What procedures are "acceptable to AMS" for in-coming and environmental microbiological testing?
- Page 12 **Third paragraph** - What will be acceptable to AMS for appropriate "corrective actions in place when test results are positive for the existence of a possible problem"? These procedures need to be identified.
- Page 12 **Microbiological Testing by AMS** - What is appropriate for the "prompt corrective action" needed to be taken if *E. coli* is detected in the product samples AMS takes? These actions need to be based on good science. *E. coli* is not pathogenic but could be an indication of possible fecal contamination. What is the appropriate response?
- Page 16 **Description of the Products and Label** - What are the procedures to approve a new product or production process for the QTV shield?
- Page 19 **Hazard Analysis** - The IFPA's document referenced in the second paragraph is correctly titled "Food Safety Guidelines for the Fresh-cut Produce Industry" published in 1996.
- Page 19-20 **Hazard Analysis** - There are many references to quality characteristics as examples in this section. We recommend that the examples be kept to a minimum to avoid confusion between quality and safety. For example, pesticides are not considered to be a chemical hazard nor is decomposed product tissue considered to be a physical hazard.
- Page 26 **Figure 6, Critical Control Point 1 - Lettuce Receiving** - This example should

be removed from the document because temperature control of the raw materials is primarily a quality issue, not a safety control. We recommend that an example of a totally different food product be used as an example of format so that there are no arguments about whether the QTV example is indeed a critical control point in every operation.

- Page 27 **Figure 6A, Critical Control Point 2 - Refrigerated Storage** - This second example is not needed for format purposes. We recommend using one example from another food group which is more than sufficient.
- Page 29 **Microbiological Testing Program** - What is meant by in-house testing and outside laboratory testing? Would it be appropriate to include procedures that are acceptable, or what is the importance? Also, what procedures are acceptable to AMS for in-coming and environmental microbiological testing?
- Page 30 **Standard Operating Procedures and Standard Testing Procedures** - These are so closely related that they would be well suited to be merged together. These should not be optional, either. The testing procedures should be referenced.
- Page 31 **Consumer Complaint Procedure** - These should only come into play if they are related to food safety. So many consumer complaints are quality related that these may confuse the issue when using them to measure the success of a food safety program. The industry may be better served not to include these in this food safety audit program.
- Page 51 **Appendix C** - This whole appendix should be completely removed from the program as there are references to quality parameters that cloud the issue and there are many suitable published papers from academia that can be cited to describe the microbiology of fresh-cut produce. The IFPA has produced a comprehensive discussion paper on this subject. There are also "Recommended Analyses" that are totally unrealistic for these products. AMS needs to identify procedures that are approved, but unless AMS has scientific reason, the tests should be left up to the processors to describe and defend.
- Page 53 **Method References** - These references should be specified as "Approved Testing Methods" with no reference to the specific tests recommended. AMS needs to stay current with industry issues to confidently identify suitable testing programs.

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Produce Marketing Association
Advancing the Produce and Floral Industries

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October 5, 1998

Office of the Branch Chief
Processed Products Branch, Fruit and Vegetable Programs
Agricultural Marketing Service, USDA
STOP 0247
P.O. Box 96456
Washington, DC 20090-6456

Re: Federal Register, Vol. 63, No. 172, Page 47220, September 4, 1998: Request for Comments on the Qualified Through Verification Program for the Fresh-Cut Produce Industry

The Produce Marketing Association is pleased to submit these remarks in response to USDA's request for comments on its Qualified Through Verification Program.

PMA is the largest worldwide not-for-profit trade association representing companies that market fresh fruits and vegetables. Our membership of more than 2,500 ranges from supermarket retailers to grower-shippers, and from hotel and restaurant chains to overseas importers. The association's membership does include fresh-cut produce processors and their suppliers (grower-shippers) and customers (food wholesalers and retailers and foodservice distributors and operators, some of which process fruits and vegetables themselves).

Within the United States, PMA's members handle more than 90% of fresh produce sold at consumer level. The association's mission is to create a favorable, responsible environment that advances the marketing of produce and floral products and services for North American buyers and sellers and their international partners.

In these comments, PMA does not intend to address every issue identified in the request for comments. Rather we specifically turn to the issue of timely review of industry applications for certification.

We understand that this program, according to USDA, provides for voluntary audit-based inspections for wholesomeness and food safety. We agree that such a program can foster a proactive approach by the production facility's management for identifying process deficiencies during production rather than after production is completed.

The notice states that "the agency reviews QTV plans in the order in

PMA
Your Competitive Edge

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Dominick's Finer Foods Inc.

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The Kroger Company

Victor Moller
HORTIFRUT S.A.

Jay Pack
Standard Fruit & Vegetable

Mike Rempe
C. H. Robinson Company

Debby Robinson
Randall's Food Markets, Inc.

Roger Schroeder
Hughes Markets

Martha L. Spezia
Lettuce Entertain You

Floyd Warner
Ben E. Keith Foods

Chip Wiechec
Hunter Brothers, Inc.

which they are received. Draft QTV plans are generally reviewed within 30 days. Later drafts, if revisions to the QTV plan are necessary, are usually reviewed within two weeks."

PMA wishes to stress the importance of adhering to such time frames for the review and certification process.

We understand that a company's progress in the program can be based on the speed with which a firm has revised its QTV plan and completed any necessary training or facility modifications. We also understand that heavy demand for USDA certification of facilities could slow the process.

Some in the industry perceive access to and maintenance of a QTV certification to be an important marketplace issue. For those companies, any delay in processing their application for the QTV certification could put them at a competitive disadvantage in the marketplace.

It is apparent that USDA recognizes this marketplace advantage – at least intuitively – by specifying that the shield may be used in an approved company's advertising and promotion. If this program offered no marketing advantage, it would not be used in advertising and promotion.

Therefore, PMA urges that USDA process and complete applications for the QTV program as quickly as possible to maintain an even playing field for those companies that want to use the program. Making sure that adequate resources are available to process these applications must be a critical part of the planning process.

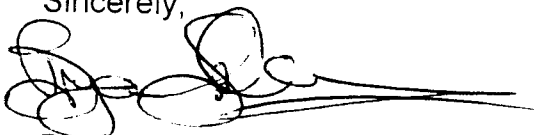
PMA offers no comments on the appearance of the shield.

We believe that USDA has clearly identified this as a food safety program, not a food quality program, as the comment notice stated that the QTV Program "provides for voluntary audit-based inspections for wholesomeness and food safety."

In addition, the comment notice states: "QTV allows AMS to provide services that help food processors develop food safety plans based on sound scientific and objective techniques such as HACCP....AMS believes that participation in QTV will help firms comply with food safety regulations."

PMA appreciates the opportunity to present these comments. Please do not hesitate to call upon us if we can be of further assistance. We look forward to working with you.

Sincerely,

A handwritten signature in black ink, appearing to read "Bryan Silberman", with a long horizontal line extending to the right.

Bryan Silberman, CAE
President
Produce Marketing Association

East Coast Fresh Cuts

7715 Assateague Drive
Jessup, MD 20794

Sept. 11, 1998

Office of the Branch Chief
Processed Products Branch,
Fruit & Vegetable Programs
USDA Stop 0247, P.O. Box 96456
Washington, DC 20090-6456

Dear Sir or Madam:


We are writing to you, as we are gravely concerned with the status of the QTV program. We are a company specializing in fresh cut fruit and vegetables. While we mainly ship to large distributors, our products reach a large number of people including many schools and hospitals. To this end, our company has invested thousands of dollars and hundreds of irreplaceable hours in order to earn the QTV shield. Personnel have attended seminars, and long term planning for the company's future has been based on attaining and keeping QTV status. We firmly believe that with such a program we will best serve our customers' needs, as well as maintaining our own high standards.

As you are interested in comments regarding "quality vs. safety", the two are interchangeable and most definitely not mutually exclusive of each other. One quick glance at our HACCP Plan, the foundation on which the QTV program is built, is enough to see that safety is of an overriding concern. True, we want the best quality: we would not be in business if we didn't, but through a safe, clean plant and products, we attain a twofold goal: a high quality item that we can guarantee is safe; safe from metal particles, harmful microbes, chemicals, wood particles, etc. The QTV shield tells our customers that they do not have to worry when they eat the salads we produce. It informs them that we have taken the responsibility of ensuring them a safe, healthy product from the field in which it is grown until it is on their table. Our responsibility does not end when our product arrives in someone's warehouse. We will not ship to a distributor that does not share our high standards and concerns.

We are puzzled that the opponents of QTV, namely the United Fresh Fruit & Vegetable Association, are not prepared to stand by their products. If they are confident in the safety of their products, then they don't need to worry about acquiring the QTV Shield. Why then, does it bother them that companies are prepared to spend money on a voluntary program? Are they afraid the government will compel them to establish a QTV program? Proponents of QTV are not asking for mandatory regulations. We are not saying our products are better. Rather, that we can guarantee the safety of what we produce. We cannot stop all food borne illness and other accidents, but at the end of the day we can safely say it did not come from our company. Can opponents of QTV make this claim?

It is our fervent hope and wish that the QTV program continues unchanged and unhindered. We have withheld our annual membership with the United Fresh Fruit & Vegetable Association, as we are totally opposed to their position. For our company, QTV remains the most effective way to guarantee the safety and quality we and our customers' demand.

Sincerely,


Jonathan Gold
Quality Assurance Manager and Mashgiach
(Kosher inspector)


Phil Muth
President, East Coast Fresh Cuts

CC. United Fresh Fruit & Vegetable Association